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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,993	03/16/2001	Shlomit Gilad	0168.00102	7309

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,993

Applicant(s)

GILAD ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003; 5/30/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed January 7, 2003. Currently, claims 1-22 are pending.
2. Upon further consideration, the examiner has determined that the claims require further restriction. A complete copy of a restriction requirement is presented below.

Maintained Rejections

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, 11-22, drawn to methods of determining if individuals have a predisposition for developing breast cancer by detecting a mutation in the ATM gene, classified in class 435, subclass 6.
 - II. Claims 7-10, drawn to an isolated cDNA, classified in class 536, subclass 23.1.
4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid may be used in a materially different method. The nucleic acid may be used in methods of analyzing sporadic T-cell leukemia as taught by Vorechovsky (Nature Genetics, Vol. 17, September 1997, pages 96-99). Moreover the nucleic acids may be used in methods of

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purification, isolation, aptamer screening methods, hybridization assays, and antisense methods.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction Requirement Applicable to All Groups:

6. The claims, namely Claims 1-22, are drawn to methods of testing an individual for breast cancer by detecting mutations in the ATM gene wherein the mutations are set forth in Table 4 and 5 and to the nucleic acid and markers. It is noted that ten of the mutations in Table 4 are not novel (i.e. references are cited for their presence). The specification, page 20, teaches that nine of the mutations are new. With respect to the product claims, the intended use does not carry patentable weight.

7. Each marker/sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

A restriction is applied to each Group. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04). The claims contains nineteen individual, independent and distinct markers and nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996). For those claims which require two or more mutations, applicant may select either a single mutation or single combination of mutations. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are

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unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Absent evidence to the contrary, one mutation within a gene does not render other mutations obvious. Therefore, the mutations are deemed patentably distinct.

The response asserts that all of the mutations are in the same gene and associated with the same disease. This argument has been thoroughly reviewed, but is not found persuasive because each of these mutations and their associations with breast cancer are patentably distinct. The presence of one association of a marker with breast cancer does not indicate the presence of another marker or its association with breast cancer. Therefore, the markers are patentably distinct.


Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.


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8. A telephone call was made to John P. White on June 17, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.
9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
June 19, 2003


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600